

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/784,528	Applicant(s) BROWN ET AL.
Examiner FEREYDOUN G. SAJJADI	Art Unit 1633

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
b) ☐ They raise the issue of new matter (see NOTE below);
c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 4, 7, 8, 15, 26 and 27.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Fereydoun G Sajjadi/
Primary Examiner, Art Unit 1633

Continuation of 3. NOTE: Applicants' proposed amendment includes new claims 28-39, directed to limitations for increasing the level of phosphorylation on serine 15 of p53, decreasing the level of cyclins A and B, increasing the level of cyclin D3, increasing the level of p53 and increasing the level of cleaved PARP, not previously presented or examined. Entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier.

Continuation of 11. does NOT place the application in condition for allowance because: The examiner maintains the rejection of claims 4,7,8,15,26 and 27 under 35 U.S.C. §112, first paragraph, because the specification fails to provide an enablement for the full scope of the claimed invention.

With reference to the working examples and various case law, Applicants argue that the Office has not provided a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application. Applicants' arguments have been fully considered, but are not found persuasive.

In response, Applicants are directed to the previous Office actions detailing the grounds for rejection, that include deficiencies in the cancer models utilized and specific teaching away from Applicants' claimed invention by the prior art.

Applicants argue the present claims are directed to inducing apoptosis in human prostate cancer or breast cancer cells; and although it is true that the present application contemplates treating a variety of cancers by induction of apoptosis, practicing the claimed invention does not require the treatment of clinical cancer. Such is not found persuasive, because Applicants' statement appears inconsistent, as

Applicants have admitted on the record that the application contemplates treating a variety of cancers by induction of apoptosis. The claims have been given the broadest reasonable interpretation in view of the as filed specification.

Applicants' arguments regarding the cancer models reviewed by Krebel and Vieweg are not found persuasive, because they clearly set forth the unpredictability of the cancer models.

Applicants' argument that Wang would not lead a skilled artisan to believe that further experimentation is needed to resolve the apparent paradox suggested by Wang when treating cancers, by stating: "over-expression of K+ channels by infection of tumour cells with virus vectors carrying K+ channel cDNAs, will be feasible sooner or later", is not found persuasive, because the statement makes it clear that such treatment is not yet feasible and the obstacles in such approach need to be overcome. An invitation for further experimentation is not indicative of an enabled disclosure.

Applicants' reference to *In re Brana*, that in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development, ignores the critical *Wands* factor of predictability, that must be considered in an enablement rejection. Further experimentation is permissible when it is merely routine and predictable, however, in the instant case, enhancement of K+ channel activity can facilitate not only tumor cell apoptosis but also tumor cell proliferation, and as indicated by Wang, this apparent paradox confounds the manipulation of K+ channel function and/or expression as an option for the treatment of cancers.

Thus, the rejection is maintained for reasons of record and the foregoing response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREDYOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.